K012239

AUG 1 0 2001

4.7 SUMMARY OF SAFETY AND EFFECTIVENESS

510(K) SUMMARY

Date Prepared
June 14, 2001

Submitter's Information
Walter Weyburne
Hitachi Medical Corporation of America
660 White Plains Road
Tarrytown, NY 10591
(914) 524-9711

Joseph M. Azary III
Azary Technologies LLC
PO Box 2156
Huntington, CT 06484
(203) 944-9320

Trade Name, Common Name, Classification
The device trade names are:

- EUB-525 Ultrasound system
- EUB-2000 Ultrasound system
- SP-711UA
- SP-711 Sonoprobe system

Predicate Device
The subject device consists of two separate assemblies. The Hitachi EUB-525/EUB-2000 Diagnostic Ultrasound Scanner and the Fujinon SP711 Sonoprobe system. The Fujinon SP711 Sonoprobe system is an optional add-on device for the Hitachi EUB-525/EUB-2000 which allows the EUB-525/EUB-2000 to utilize the Fujinon probes.

The Hitachi EUB-525 Diagnostic Ultrasound Scanner has previously been cleared by the FDA under 510(k) K981434. The Hitachi EUB-2000 was introduced as a modification of the EUB-525 under Appendix E of *Information for Manufacturers Seeking Marketing Clearance of Diagnostic Ultrasound Systems and Transducers*, dated September 30, 1997. The Fujinon SP711 Sonoprobe system was previously cleared for use with the Hitachi EUB-6000 by the FDA under 510(k) K011252.

Description Of The Device
The subject device consists of:

- EUB-525/EUB-2000 Diagnostic Ultrasound Scanner
- SP-711UA Ultrasonic Probe Connecting Unit
- TL-1A Translator
- Probe (PL Series or PL26-7.5 Series)
- Balloon and Sheath

The Hitachi EUB-525/EUB-2000 operating controls and their associated functions do not change with the addition of the Fujinon SP-711 Sonoprobe system. The operating controls specific to the Fujinon SP-711 system are described in the operation manuals included with this document in Section 7.

The transducers subject to this submission are the same transducers described in the previously cleared 510(k) K011252. They are:

PL1726-20	PL1726-15	PL1726-12	PL1726-7.5
PL1926-20	PL1926-15	PL1926-12	PL1926-7.5
PL2226-20	PL2226-15	PL2226-12	PL2226-7.5
PL2220-20	PL2220-15	PL2220-12	

The PL26-7.5 probe series includes one type for use with a balloon/sheath and the other type for use without a balloon. The only difference between probes is the structure of the tip. The probes made for use with a balloon/sheath have a groove on the tip to catch the balloon head. The probes made for use without a balloon are slightly shorter. The choice of the probe type is at the discretion of the physician. Since ultrasound waves are stronger in water, the physician may choose to use the balloon version to improve image quality. The probes made for use with a balloon/sheath are designated with a "B" (i.e. PL26B-7.5) and must be used with a balloon adapter, balloon sheath, and balloon as described in the operation manual.

Intended Use
Identical to device previously cleared by the FDA under 510(k) K011252.
The intended use of the subject device is for endoscopic observation of the gastrointestinal tract (esophagus, stomach, duodenum, large intestine) and biliary system (pancreato-biliary ducts). The Ultrasound Device Indications Statements for each application and mode of the system/transducers are included with this document.

Technological Characteristics
Identical to device previously cleared by the FDA under 510(k) K011252.

Performance Data
Identical to device previously cleared by the FDA under 510(k) K011252.

Conclusion
We conclude that the subject device is as safe and effective as the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 1 0 2001

Mr. Walter Weyburne
Regulatory Affairs
Hitachi Medical Corporation of America
Hitachi Medical Systems
660 White Plains Road
TARRYTOWN NY 10591-5107

Re: K012239
Trade Name: EUB-525/EUB-2000 Diagnostic Ultrasound Scanner with Fujinon SP711UA/SP711 Sonoprobe System
Regulatory Class: II/21 CFR 892.1550
Product Code: 90 IYN
Regulatory Class: II/21 CFR 892.1560
Product Code: 90 IYO
Dated: July 16, 2001
Received: July 17, 2001

Dear Mr. Weyburne:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28,1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

This determination of substantial equivalence applies to the following transducers intended for use with the EUB-525/EUB-2000 Diagnostic Ultrasound Scanner, as described in your premarket notification:

Transducer Model Number
PL1726-20
PL1926-20
PL2226-20
PL2220-20
PL1726-15
PL1926-15
PL2226-15
PL2220-15
PL1726-12
PL1926-12
PL2226-12

PL2220-12
PL1726-7.5
PL1926-7.5
PL2226-7.5

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval) it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General (GMP) regulation (21 CFR Part 820) and that, through periodic QS inspections, the FDA will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, the Food and Drug Administration (FDA) may publish further announcements concerning your device in the Federal Register. *Please note*: this response to your premarket notification does not affect any obligation you may have under sections 531 and 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus permits your device to proceed to market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4591. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or at (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsmamain.html".

If you have any questions regarding the content of this letter, please contact Rodrigo C. Perez at (301) 594-1212.

Sincerely yours,

Nancy C. Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure(s)

K012239

4.3 INDICATIONS FOR USE

Diagnostic Ultrasound Indications for Use Form

System/Transducer: EUB-525/EUB-2000 System

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation							
General (Track 1 only)	Specific (Tracks I & III)	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Combined* (specify)	Other** (specify)
Ophthalmic	Ophthalmic								
Fetal Imaging & Others	Fetal	P	P	P	P	P	P	N	P
	Abdominal	Pa	Pa	Pa	Pa	Pa	Pa	Na	Pa
	Intraoperative (specify)	Pb	Pb	Pb		Pb	Pb	Nb	Pb
	Intraoperative (Neuro.)								
	Laparoscopic	P	P	P		P	P	N	P
	Pediatric	P	P	P	P	P	P	N	P
	Small Organ (specify)	Pd	Pd	Pd		Pd	Pd	Nd	Pd
	Neonatal Cephalic	P	P	P		P	P	N	P
	Adult Cephalic								
	Trans-rectal	Ph	Ph	Ph		Ph	Ph	Nh	Ph
	Trans-vaginal	Pf	Pf	Pf		Pf	Pf	Nf	Pf
	Trans-urethral								
	Trans-esophageal								
	Muskulo-skeletal Conventional								
	Musculo-skeletal Superficial								
	Intra-luminal	Ni							
	Other (specify)								
Cardiac	Cardiac Adult	P	P	P	P	P	P	N	P
	Cardiac Pediatric	P	P	P	P	P	P	N	P
	Cardiac Transesophageal Adult	P	P	P		P	P	N	P
	Cardiac Transesophageal Pediatric	P	P	P		P	P	N	P
	Other (specify)								
Peripheral Vessel	Peripheral Vascular	P	P	P		P	P	N	P
	Other (specify)								

N=new indication; P=previously cleared by FDA under 510(k)# **K981434**; E=added under appendix E

*Combination of each operating mode, B, M, PWD, CWD, and Color Doppler

**Amplitude Doppler and Harmonic Imaging

Additional Comments:

Subscript "a": Includes imaging for guidance of percutaneous biopsy of abdominal organs and structures (including amniocentesis).

Subscript "b": Includes imaging of organs and structures exposed during surgery (excluding neurosurgery and laparoscopic procedures).

Subscript "c": Includes thyroid, parathyroid, breast, scrotum, penis.

Subscript "d": Includes thyroid, parathyroid, breast, scrotum, penis and imaging for guidance of biopsy.

Subscript "e": Includes imaging for guidance of transrectal biopsy.

Subscript "f": Includes imaging for guidance of tranvaginal biopsy.

Subscript "g": For pediatric patients.

Subscript "h": Includes imaging for guidance of transrectal biopsy, cryosurgery, and brachytherapy.

Subscript "i": Includes imaging of the biliary system (pancreato-biliary) and gastrointestinal tract (esophagus, stomach, duodenum, and large intestine).

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Nancy C Brogdon

(Division Sign-Off)

Division of Reproductive, Abdominal, ENT, And Radiological Devices

510(k) Number: K012239

Prescription Use (Per 21 CFR 801.109)

4.3 INDICATIONS FOR USE

Diagnostic Ultrasound Indications for Use Form

System/Transducer: PL1726-20

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation							
General (Track 1 only)	Specific (Tracks I & III)	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Combined* (specify)	Other** (specify)
Ophthalmic	Ophthalmic								
Fetal Imaging & Others	Fetal								
	Abdominal								
	Intraoperative (specify)								
	Intraoperative (Neuro.)								
	Laparoscopic								
	Pediatric								
	Small Organ (specify)								
	Neonatal Cephalic								
	Adult Cephalic								
	Trans-rectal								
	Trans-vaginal								
	Trans-urethral								
	Trans-esophageal								
	Muskulo-skeletal Conventional								
	Musculo-skeletal Superficial								
	Intra-luminal	Pi							
	Other (specify)								
Cardiac	Cardiac Adult								
	Cardiac Pediatric								
	Cardiac Transesophageal Adult								
	Cardiac Transesophageal Pediatric								
	Other (specify)								
Peripheral Vessel	Peripheral Vascular								
	Other (specify)								

N=new indication; P=previously cleared by FDA under 510(k)# **K011252**; E=added under appendix E

*Combination of each operating mode, B, M, PWD, CWD, and Color Doppler

**Amplitude Doppler and Harmonic Imaging

Additional Comments:

Subscript "a": Includes imaging for guidance of percutaneous biopsy of abdominal organs and structures (including amniocentesis).

Subscript "b": Includes imaging of organs and structures exposed during surgery (excluding neurosurgery and laparoscopic procedures).

Subscript "c": Includes thyroid, parathyroid, breast, scrotum, penis.

Subscript "d": Includes thyroid, parathyroid, breast, scrotum, penis and imaging for guidance of biopsy.

Subscript "e": Includes imaging for guidance of transrectal biopsy.

Subscript "f": Includes imaging for guidance of tranvaginal biopsy.

Subscript "g": For pediatric patients.

Subscript "h": Includes imaging for guidance of transrectal biopsy, cryosurgery, and brachytherapy.

Subscript "i": Includes imaging of the biliary system (pancreato-biliary) and gastrointestinal tract (esophagus, stomach, duodenum, and large intestine).

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Concurrence of CDRH, Office of Device Evaluation (ODE)

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(Division Sign-Off)

Division of Reproductive, Abdominal, ENT,
And Radiological Devices

510(k) Number: K012239

Prescription Use (Per 21 CFR 801.109)

4.3 INDICATIONS FOR USE

Diagnostic Ultrasound Indications for Use Form

System/Transducer: PL1726-15

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation							
General (Track 1 only)	Specific (Tracks I & III)	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Combined* (specify)	Other** (specify)
Ophthalmic	Ophthalmic								
Fetal Imaging & Others	Fetal								
	Abdominal								
	Intraoperative (specify)								
	Intraoperative (Neuro.)								
	Laparoscopic								
	Pediatric								
	Small Organ (specify)								
	Neonatal Cephalic								
	Adult Cephalic								
	Trans-rectal								
	Trans-vaginal								
	Trans-urethral								
	Trans-esophageal								
	Muskulo-skeletal Conventional								
	Musculo-skeletal Superficial								
	Intra-luminal	Pi							
	Other (specify)								
Cardiac	Cardiac Adult								
	Cardiac Pediatric								
	Cardiac Transesophageal Adult								
	Cardiac Transesophageal Pediatric								
	Other (specify)								
Peripheral Vessel	Peripheral Vascular								
	Other (specify)								

N=new indication; P=previously cleared by FDA under 510(k)# **K011252**; E=added under appendix E

*Combination of each operating mode, B, M, PWD, CWD, and Color Doppler

**Amplitude Doppler and Harmonic Imaging

Additional Comments:

Subscript "a": Includes imaging for guidance of percutaneous biopsy of abdominal organs and structures (including amniocentesis).

Subscript "b": Includes imaging of organs and structures exposed during surgery (excluding neurosurgery and laparoscopic procedures).

Subscript "c": Includes thyroid, parathyroid, breast, scrotum, penis.

Subscript "d": Includes thyroid, parathyroid, breast, scrotum, penis and imaging for guidance of biopsy.

Subscript "e": Includes imaging for guidance of transrectal biopsy.

Subscript "f": Includes imaging for guidance of tranvaginal biopsy.

Subscript "g": For pediatric patients.

Subscript "h": Includes imaging for guidance of transrectal biopsy, cryosurgery, and brachytherapy.

Subscript "i": Includes imaging of the biliary system (pancreato-biliary) and gastrointestinal tract (esophagus, stomach, duodenum, and large intestine).

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Concurrence of CDRH, Office of Device Evaluation (ODE)

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Division of Reproductive, Abdominal, ENT,
And Radiological Devices

510(k) Number: K012239

Prescription Use (Per 21 CFR 801.109)

4.3 INDICATIONS FOR USE

Diagnostic Ultrasound Indications for Use Form

System/Transducer: PL1726-12

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation							
General (Track 1 only)	Specific (Tracks I & III)	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Combined* (specify)	Other** (specify)
Ophthalmic	Ophthalmic								
Fetal Imaging & Others	Fetal								
	Abdominal								
	Intraoperative (specify)								
	Intraoperative (Neuro.)								
	Laparoscopic								
	Pediatric								
	Small Organ (specify)								
	Neonatal Cephalic								
	Adult Cephalic								
	Trans-rectal								
	Trans-vaginal								
	Trans-urethral								
	Trans-esophageal								
	Muskulo-skeletal Conventional								
	Musculo-skeletal Superficial								
	Intra-luminal	Pi							
	Other (specify)								
Cardiac	Cardiac Adult								
	Cardiac Pediatric								
	Cardiac Transesophageal Adult								
	Cardiac Transesophageal Pediatric								
	Other (specify)								
Peripheral Vessel	Peripheral Vascular								
	Other (specify)								

N=new indication; P=previously cleared by FDA under 510(k)# **K011252**; E=added under appendix E

*Combination of each operating mode, B, M, PWD, CWD, and Color Doppler

**Amplitude Doppler and Harmonic Imaging

Additional Comments:

Subscript "a": Includes imaging for guidance of percutaneous biopsy of abdominal organs and structures (including amniocentesis).

Subscript "b": Includes imaging of organs and structures exposed during surgery (excluding neurosurgery and laparoscopic procedures).

Subscript "c": Includes thyroid, parathyroid, breast, scrotum, penis.

Subscript "d": Includes thyroid, parathyroid, breast, scrotum, penis and imaging for guidance of biopsy.

Subscript "e": Includes imaging for guidance of transrectal biopsy.

Subscript "f": Includes imaging for guidance of tranvaginal biopsy.

Subscript "g": For pediatric patients.

Subscript "h": Includes imaging for guidance of transrectal biopsy, cryosurgery, and brachytherapy.

Subscript "i": Includes imaging of the biliary system (pancreato-biliary) and gastrointestinal tract (esophagus, stomach, duodenum, and large intestine).

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Concurrence of CDRH, Office of Device Evaluation (ODE)

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Division of Reproductive, Abdominal, ENT, And Radiological Devices

510(k) Number: K012239

Prescription Use (Per 21 CFR 801.109)

4.3 INDICATIONS FOR USE

Diagnostic Ultrasound Indications for Use Form

System/Transducer: PL1726-7.5

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation							
General (Track 1 only)	Specific (Tracks I & III)	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Combined* (specify)	Other** (specify)
Ophthalmic	Ophthalmic								
Fetal Imaging & Others	Fetal								
	Abdominal								
	Intraoperative (specify)								
	Intraoperative (Neuro.)								
	Laparoscopic								
	Pediatric								
	Small Organ (specify)								
	Neonatal Cephalic								
	Adult Cephalic								
	Trans-rectal								
	Trans-vaginal								
	Trans-urethral								
	Trans-esophageal								
	Muskulo-skeletal Conventional								
	Musculo-skeletal Superficial								
	Intra-luminal	Pi							
	Other (specify)								
Cardiac	Cardiac Adult								
	Cardiac Pediatric								
	Cardiac Transesophageal Adult								
	Cardiac Transesophageal Pediatric								
	Other (specify)								
Peripheral Vessel	Peripheral Vascular								
	Other (specify)								

N=new indication; P=previously cleared by FDA under 510(k)# **K011252**; E=added under appendix E

*Combination of each operating mode, B, M, PWD, CWD, and Color Doppler

**Amplitude Doppler and Harmonic Imaging

Additional Comments:

Subscript "a": Includes imaging for guidance of percutaneous biopsy of abdominal organs and structures (including amniocentesis).

Subscript "b": Includes imaging of organs and structures exposed during surgery (excluding neurosurgery and laparoscopic procedures).

Subscript "c": Includes thyroid, parathyroid, breast, scrotum, penis.

Subscript "d": Includes thyroid, parathyroid, breast, scrotum, penis and imaging for guidance of biopsy.

Subscript "e": Includes imaging for guidance of transrectal biopsy.

Subscript "f": Includes imaging for guidance of tranvaginal biopsy.

Subscript "g": For pediatric patients.

Subscript "h": Includes imaging for guidance of transrectal biopsy, cryosurgery, and brachytherapy.

Subscript "i": Includes imaging of the biliary system (pancreato-biliary) and gastrointestinal tract (esophagus, stomach, duodenum, and large intestine).

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Concurrence of CDRH, Office of Device Evaluation (ODE)

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Division of Reproductive, Abdominal, ENT, And Radiological Devices

510(k) Number: K012239

Prescription Use (Per 21 CFR 801.109)

4.3 INDICATIONS FOR USE

Diagnostic Ultrasound Indications for Use Form

System/Transducer: PL1926-20

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation							
General (Track 1 only)	Specific (Tracks I & III)	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Combined* (specify)	Other** (specify)
Ophthalmic	Ophthalmic								
Fetal Imaging & Others	Fetal								
	Abdominal								
	Intraoperative (specify)								
	Intraoperative (Neuro.)								
	Laparoscopic								
	Pediatric								
	Small Organ (specify)								
	Neonatal Cephalic								
	Adult Cephalic								
	Trans-rectal								
	Trans-vaginal								
	Trans-urethral								
	Trans-esophageal								
	Muskulo-skeletal Conventional								
	Musculo-skeletal Superficial								
	Intra-luminal	Pi							
	Other (specify)								
Cardiac	Cardiac Adult								
	Cardiac Pediatric								
	Cardiac Transesophageal Adult								
	Cardiac Transesophageal Pediatric								
	Other (specify)								
Peripheral Vessel	Peripheral Vascular								
	Other (specify)								

N=new indication; P=previously cleared by FDA under 510(k)# **K011252**; E=added under appendix E

*Combination of each operating mode, B, M, PWD, CWD, and Color Doppler

**Amplitude Doppler and Harmonic Imaging

Additional Comments:

Subscript "a": Includes imaging for guidance of percutaneous biopsy of abdominal organs and structures (including amniocentesis).

Subscript "b": Includes imaging of organs and structures exposed during surgery (excluding neurosurgery and laparoscopic procedures).

Subscript "c": Includes thyroid, parathyroid, breast, scrotum, penis.

Subscript "d": Includes thyroid, parathyroid, breast, scrotum, penis and imaging for guidance of biopsy.

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Subscript "g": For pediatric patients.

Subscript "h": Includes imaging for guidance of transrectal biopsy, cryosurgery, and brachytherapy.

Subscript "i": Includes imaging of the biliary system (pancreato-biliary) and gastrointestinal tract (esophagus, stomach, duodenum, and large intestine).

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Nancy C. Brogdon

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT,
And Radiological Devices

510(k) Number: K012239

Prescription Use (Per 21 CFR 801.109)

4.3 INDICATIONS FOR USE

Diagnostic Ultrasound Indications for Use Form

System/Transducer: PL1926-15

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation							
General (Track 1 only)	Specific (Tracks I & III)	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Combined* (specify)	Other** (specify)
Ophthalmic	Ophthalmic								
Fetal Imaging & Others	Fetal								
	Abdominal								
	Intraoperative (specify)								
	Intraoperative (Neuro.)								
	Laparoscopic								
	Pediatric								
	Small Organ (specify)								
	Neonatal Cephalic								
	Adult Cephalic								
	Trans-rectal								
	Trans-vaginal								
	Trans-urethral								
	Trans-esophageal								
	Muskulo-skeletal Conventional								
	Musculo-skeletal Superficial								
	Intra-luminal	Pi							
	Other (specify)								
Cardiac	Cardiac Adult								
	Cardiac Pediatric								
	Cardiac Transesophageal Adult								
	Cardiac Transesophageal Pediatric								
	Other (specify)								
Peripheral Vessel	Peripheral Vascular								
	Other (specify)								

N=new indication; P=previously cleared by FDA under 510(k)# **K011252**; E=added under appendix E

*Combination of each operating mode, B, M, PWD, CWD, and Color Doppler

**Amplitude Doppler and Harmonic Imaging

Additional Comments:

Subscript "a": Includes imaging for guidance of percutaneous biopsy of abdominal organs and structures (including amniocentesis).

Subscript "b": Includes imaging of organs and structures exposed during surgery (excluding neurosurgery and laparoscopic procedures).

Subscript "c": Includes thyroid, parathyroid, breast, scrotum, penis.

Subscript "d": Includes thyroid, parathyroid, breast, scrotum, penis and imaging for guidance of biopsy.

Subscript "e": Includes imaging for guidance of transrectal biopsy.

Subscript "f": Includes imaging for guidance of tranvaginal biopsy.

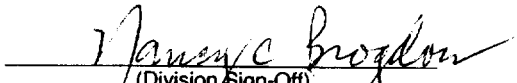
Subscript "g": For pediatric patients.

Subscript "h": Includes imaging for guidance of transrectal biopsy, cryosurgery, and brachytherapy.

Subscript "i": Includes imaging of the biliary system (pancreato-biliary) and gastrointestinal tract (esophagus, stomach, duodenum, and large intestine).

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)



(Division Sign-Off)

Division of Reproductive, Abdominal, ENT, And Radiological Devices

510(k) Number: K012239

Prescription Use (Per 21 CFR 801.109)

4.3 INDICATIONS FOR USE

Diagnostic Ultrasound Indications for Use Form

System/Transducer: PL1926-12

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation							
General (Track 1 only)	Specific (Tracks I & III)	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Combined* (specify)	Other** (specify)
Ophthalmic	Ophthalmic								
Fetal Imaging & Others	Fetal								
	Abdominal								
	Intraoperative (specify)								
	Intraoperative (Neuro.)								
	Laparoscopic								
	Pediatric								
	Small Organ (specify)								
	Neonatal Cephalic								
	Adult Cephalic								
	Trans-rectal								
	Trans-vaginal								
	Trans-urethral								
	Trans-esophageal								
	Muskulo-skeletal Conventional								
	Musculo-skeletal Superficial								
	Intra-luminal	Pi							
	Other (specify)								
Cardiac	Cardiac Adult								
	Cardiac Pediatric								
	Cardiac Transesophageal Adult								
	Cardiac Transesophageal Pediatric								
	Other (specify)								
Peripheral Vessel	Peripheral Vascular								
	Other (specify)								

N=new indication; P=previously cleared by FDA under 510(k)# **K011252**; E=added under appendix E

*Combination of each operating mode, B, M, PWD, CWD, and Color Doppler

**Amplitude Doppler and Harmonic Imaging

Additional Comments:

Subscript "a": Includes imaging for guidance of percutaneous biopsy of abdominal organs and structures (including amniocentesis).

Subscript "b": Includes imaging of organs and structures exposed during surgery (excluding neurosurgery and laparoscopic procedures).

Subscript "c": Includes thyroid, parathyroid, breast, scrotum, penis.

Subscript "d": Includes thyroid, parathyroid, breast, scrotum, penis and imaging for guidance of biopsy.

Subscript "e": Includes imaging for guidance of transrectal biopsy.

Subscript "f": Includes imaging for guidance of tranvaginal biopsy.

Subscript "g": For pediatric patients.

Subscript "h": Includes imaging for guidance of transrectal biopsy, cryosurgery, and brachytherapy.

Subscript "i": Includes imaging of the biliary system (pancreato-biliary) and gastrointestinal tract (esophagus, stomach, duodenum, and large intestine).

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Concurrence of CDRH, Office of Device Evaluation (ODE)

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Division of Reproductive, Abdominal, ENT,
And Radiological Devices

510(k) Number: K012239

Prescription Use (Per 21 CFR 801.109)

4.3 INDICATIONS FOR USE

Diagnostic Ultrasound Indications for Use Form

System/Transducer: PL1926-7.5

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation							
General (Track 1 only)	Specific (Tracks I & III)	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Combined* (specify)	Other** (specify)
Ophthalmic	Ophthalmic								
Fetal Imaging & Others	Fetal								
	Abdominal								
	Intraoperative (specify)								
	Intraoperative (Neuro.)								
	Laparoscopic								
	Pediatric								
	Small Organ (specify)								
	Neonatal Cephalic								
	Adult Cephalic								
	Trans-rectal								
	Trans-vaginal								
	Trans-urethral								
	Trans-esophageal								
	Muskulo-skeletal Conventional								
	Musculo-skeletal Superficial								
	Intra-luminal	Pi							
	Other (specify)								
Cardiac	Cardiac Adult								
	Cardiac Pediatric								
	Cardiac Transesophageal Adult								
	Cardiac Transesophageal Pediatric								
	Other (specify)								
Peripheral Vessel	Peripheral Vascular								
	Other (specify)								

N=new indication; P=previously cleared by FDA under 510(k)# **K011252**; E=added under appendix E

*Combination of each operating mode, B, M, PWD, CWD, and Color Doppler

**Amplitude Doppler and Harmonic Imaging

Additional Comments:

Subscript "a": Includes imaging for guidance of percutaneous biopsy of abdominal organs and structures (including amniocentesis).

Subscript "b": Includes imaging of organs and structures exposed during surgery (excluding neurosurgery and laparoscopic procedures).

Subscript "c": Includes thyroid, parathyroid, breast, scrotum, penis.

Subscript "d": Includes thyroid, parathyroid, breast, scrotum, penis and imaging for guidance of biopsy.

Subscript "e": Includes imaging for guidance of transrectal biopsy.

Subscript "f": Includes imaging for guidance of tranvaginal biopsy.

Subscript "g": For pediatric patients.

Subscript "h": Includes imaging for guidance of transrectal biopsy, cryosurgery, and brachytherapy.

Subscript "i": Includes imaging of the biliary system (pancreato-biliary) and gastrointestinal tract (esophagus, stomach, duodenum, and large intestine).

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510(k) Number: K012239

Prescription Use (Per 21 CFR 801.109)

4.3 INDICATIONS FOR USE

Diagnostic Ultrasound Indications for Use Form

System/Transducer: PL2226-20

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation							
General (Track 1 only)	Specific (Tracks I & III)	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Combined* (specify)	Other** (specify)
Ophthalmic	Ophthalmic								
Fetal Imaging & Others	Fetal								
	Abdominal								
	Intraoperative (specify)								
	Intraoperative (Neuro.)								
	Laparoscopic								
	Pediatric								
	Small Organ (specify)								
	Neonatal Cephalic								
	Adult Cephalic								
	Trans-rectal								
	Trans-vaginal								
	Trans-urethral								
	Trans-esophageal								
	Muskulo-skeletal Conventional								
	Musculo-skeletal Superficial								
	Intra-luminal	Pi							
	Other (specify)								
Cardiac	Cardiac Adult								
	Cardiac Pediatric								
	Cardiac Transesophageal Adult								
	Cardiac Transesophageal Pediatric								
	Other (specify)								
Peripheral Vessel	Peripheral Vascular								
	Other (specify)								

N=new indication; P=previously cleared by FDA under 510(k)# **K011252**; E=added under appendix E

*Combination of each operating mode, B, M, PWD, CWD, and Color Doppler

**Amplitude Doppler and Harmonic Imaging

Additional Comments:

Subscript "a": Includes imaging for guidance of percutaneous biopsy of abdominal organs and structures (including amniocentesis).

Subscript "b": Includes imaging of organs and structures exposed during surgery (excluding neurosurgery and laparoscopic procedures).

Subscript "c": Includes thyroid, parathyroid, breast, scrotum, penis.

Subscript "d": Includes thyroid, parathyroid, breast, scrotum, penis and imaging for guidance of biopsy.

Subscript "e": Includes imaging for guidance of transrectal biopsy.

Subscript "f": Includes imaging for guidance of tranvaginal biopsy.

Subscript "g": For pediatric patients.

Subscript "h": Includes imaging for guidance of transrectal biopsy, cryosurgery, and brachytherapy.

Subscript "i": Includes imaging of the biliary system (pancreato-biliary) and gastrointestinal tract (esophagus, stomach, duodenum, and large intestine).

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510(k) Number: K012239

Prescription Use (Per 21 CFR 801.109)

4.3 INDICATIONS FOR USE

Diagnostic Ultrasound Indications for Use Form

System/Transducer: PL2226-15

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation							
General (Track 1 only)	Specific (Tracks I & III)	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Combined* (specify)	Other** (specify)
Ophthalmic	Ophthalmic								
Fetal Imaging & Others	Fetal								
	Abdominal								
	Intraoperative (specify)								
	Intraoperative (Neuro.)								
	Laparoscopic								
	Pediatric								
	Small Organ (specify)								
	Neonatal Cephalic								
	Adult Cephalic								
	Trans-rectal								
	Trans-vaginal								
	Trans-urethral								
	Trans-esophageal								
	Muskulo-skeletal Conventional								
	Musculo-skeletal Superficial								
	Intra-luminal	Pi							
	Other (specify)								
Cardiac	Cardiac Adult								
	Cardiac Pediatric								
	Cardiac Transesophageal Adult								
	Cardiac Transesophageal Pediatric								
	Other (specify)								
Peripheral Vessel	Peripheral Vascular								
	Other (specify)								

N=new indication; P=previously cleared by FDA under 510(k)# **K011252**; E=added under appendix E

*Combination of each operating mode, B, M, PWD, CWD, and Color Doppler

**Amplitude Doppler and Harmonic Imaging

Additional Comments:

Subscript "a": Includes imaging for guidance of percutaneous biopsy of abdominal organs and structures (including amniocentesis).

Subscript "b": Includes imaging of organs and structures exposed during surgery (excluding neurosurgery and laparoscopic procedures).

Subscript "c": Includes thyroid, parathyroid, breast, scrotum, penis.

Subscript "d": Includes thyroid, parathyroid, breast, scrotum, penis and imaging for guidance of biopsy.

Subscript "e": Includes imaging for guidance of transrectal biopsy.

Subscript "f": Includes imaging for guidance of tranvaginal biopsy.

Subscript "g": For pediatric patients.

Subscript "h": Includes imaging for guidance of transrectal biopsy, cryosurgery, and brachytherapy.

Subscript "i": Includes imaging of the biliary system (pancreato-biliary) and gastrointestinal tract (esophagus, stomach, duodenum, and large intestine).

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510(k) Number: K012239

Prescription Use (Per 21 CFR 801.109)

4.3 INDICATIONS FOR USE

Diagnostic Ultrasound Indications for Use Form

System/Transducer: PL2226-12

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation							
General (Track 1 only)	Specific (Tracks I & III)	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Combined* (specify)	Other** (specify)
Ophthalmic	Ophthalmic								
Fetal Imaging & Others	Fetal								
	Abdominal								
	Intraoperative (specify)								
	Intraoperative (Neuro.)								
	Laparoscopic								
	Pediatric								
	Small Organ (specify)								
	Neonatal Cephalic								
	Adult Cephalic								
	Trans-rectal								
	Trans-vaginal								
	Trans-urethral								
	Trans-esophageal								
	Muskulo-skeletal Conventional								
	Musculo-skeletal Superficial								
	Intra-luminal	Pi							
	Other (specify)								
Cardiac	Cardiac Adult								
	Cardiac Pediatric								
	Cardiac Transesophageal Adult								
	Cardiac Transesophageal Pediatric								
	Other (specify)								
Peripheral Vessel	Peripheral Vascular								
	Other (specify)								

N=new indication; P=previously cleared by FDA under 510(k)# **K011252**; E=added under appendix E

*Combination of each operating mode, B, M, PWD, CWD, and Color Doppler

**Amplitude Doppler and Harmonic Imaging

Additional Comments:

Subscript "a": Includes imaging for guidance of percutaneous biopsy of abdominal organs and structures (including amniocentesis).

Subscript "b": Includes imaging of organs and structures exposed during surgery (excluding neurosurgery and laparoscopic procedures).

Subscript "c": Includes thyroid, parathyroid, breast, scrotum, penis.

Subscript "d": Includes thyroid, parathyroid, breast, scrotum, penis and imaging for guidance of biopsy.

Subscript "e": Includes imaging for guidance of transrectal biopsy.

Subscript "f": Includes imaging for guidance of tranvaginal biopsy.

Subscript "g": For pediatric patients.

Subscript "h": Includes imaging for guidance of transrectal biopsy, cryosurgery, and brachytherapy.

Subscript "i": Includes imaging of the biliary system (pancreato-biliary) and gastrointestinal tract (esophagus, stomach, duodenum, and large intestine).

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510(k) Number: K012239

Prescription Use (Per 21 CFR 801.109)

4.3 INDICATIONS FOR USE

Diagnostic Ultrasound Indications for Use Form

System/Transducer: PL2226-7.5

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation							
General (Track 1 only)	Specific (Tracks I & III)	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Combined* (specify)	Other** (specify)
Ophthalmic	Ophthalmic								
Fetal Imaging & Others	Fetal								
	Abdominal								
	Intraoperative (specify)								
	Intraoperative (Neuro.)								
	Laparoscopic								
	Pediatric								
	Small Organ (specify)								
	Neonatal Cephalic								
	Adult Cephalic								
	Trans-rectal								
	Trans-vaginal								
	Trans-urethral								
	Trans-esophageal								
	Muskulo-skeletal Conventional								
	Musculo-skeletal Superficial								
	Intra-luminal	Pi							
	Other (specify)								
Cardiac	Cardiac Adult								
	Cardiac Pediatric								
	Cardiac Transesophageal Adult								
	Cardiac Transesophageal Pediatric								
	Other (specify)								
Peripheral Vessel	Peripheral Vascular								
	Other (specify)								

N=new indication; P=previously cleared by FDA under 510(k)# K011252; E=added under appendix E

*Combination of each operating mode, B, M, PWD, CWD, and Color Doppler

**Amplitude Doppler and Harmonic Imaging

Additional Comments:

Subscript "a": Includes imaging for guidance of percutaneous biopsy of abdominal organs and structures (including amniocentesis).

Subscript "b": Includes imaging of organs and structures exposed during surgery (excluding neurosurgery and laparoscopic procedures).

Subscript "c": Includes thyroid, parathyroid, breast, scrotum, penis.

Subscript "d": Includes thyroid, parathyroid, breast, scrotum, penis and imaging for guidance of biopsy.

Subscript "e": Includes imaging for guidance of transrectal biopsy.

Subscript "f": Includes imaging for guidance of tranvaginal biopsy.

Subscript "g": For pediatric patients.

Subscript "h": Includes imaging for guidance of transrectal biopsy, cryosurgery, and brachytherapy.

Subscript "i": Includes imaging of the biliary system (pancreato-biliary) and gastrointestinal tract (esophagus, stomach, duodenum, and large intestine).

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4.3 INDICATIONS FOR USE

Diagnostic Ultrasound Indications for Use Form

System/Transducer: PL2220-20

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation							
General (Track 1 only)	Specific (Tracks I & III)	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Combined* (specify)	Other** (specify)
Ophthalmic	Ophthalmic								
Fetal Imaging & Others	Fetal								
	Abdominal								
	Intraoperative (specify)								
	Intraoperative (Neuro.)								
	Laparoscopic								
	Pediatric								
	Small Organ (specify)								
	Neonatal Cephalic								
	Adult Cephalic								
	Trans-rectal								
	Trans-vaginal								
	Trans-urethral								
	Trans-esophageal								
	Muskulo-skeletal Conventional								
	Musculo-skeletal Superficial								
	Intra-luminal	Pi							
	Other (specify)								
Cardiac	Cardiac Adult								
	Cardiac Pediatric								
	Cardiac Transesophageal Adult								
	Cardiac Transesophageal Pediatric								
	Other (specify)								
Peripheral Vessel	Peripheral Vascular								
	Other (specify)								

N=new indication; P=previously cleared by FDA under 510(k)# **K011252**; E=added under appendix E

*Combination of each operating mode, B, M, PWD, CWD, and Color Doppler

**Amplitude Doppler and Harmonic Imaging

Additional Comments:

Subscript "a": Includes imaging for guidance of percutaneous biopsy of abdominal organs and structures (including amniocentesis).

Subscript "b": Includes imaging of organs and structures exposed during surgery (excluding neurosurgery and laparoscopic procedures).

Subscript "c": Includes thyroid, parathyroid, breast, scrotum, penis.

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Subscript "e": Includes imaging for guidance of transrectal biopsy.

Subscript "f": Includes imaging for guidance of tranvaginal biopsy.

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Subscript "h": Includes imaging for guidance of transrectal biopsy, cryosurgery, and brachytherapy.

Subscript "i": Includes imaging of the biliary system (pancreato-biliary) and gastrointestinal tract (esophagus, stomach, duodenum, and large intestine).

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510(k) Number: K012239

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4.3 INDICATIONS FOR USE

Diagnostic Ultrasound Indications for Use Form

System/Transducer: PL2220-15

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation							
General (Track 1 only)	Specific (Tracks I & III)	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Combined* (specify)	Other** (specify)
Ophthalmic	Ophthalmic								
Fetal Imaging & Others	Fetal								
	Abdominal								
	Intraoperative (specify)								
	Intraoperative (Neuro.)								
	Laparoscopic								
	Pediatric								
	Small Organ (specify)								
	Neonatal Cephalic								
	Adult Cephalic								
	Trans-rectal								
	Trans-vaginal								
	Trans-urethral								
	Trans-esophageal								
	Muskulo-skeletal Conventional								
	Musculo-skeletal Superficial								
	Intra-luminal	Pi							
	Other (specify)								
Cardiac	Cardiac Adult								
	Cardiac Pediatric								
	Cardiac Transesophageal Adult								
	Cardiac Transesophageal Pediatric								
	Other (specify)								
Peripheral Vessel	Peripheral Vascular								
	Other (specify)								

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*Combination of each operating mode, B, M, PWD, CWD, and Color Doppler

**Amplitude Doppler and Harmonic Imaging

Additional Comments:

Subscript "a": Includes imaging for guidance of percutaneous biopsy of abdominal organs and structures (including amniocentesis).

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Subscript "f": Includes imaging for guidance of tranvaginal biopsy.

Subscript "g": For pediatric patients.

Subscript "h": Includes imaging for guidance of transrectal biopsy, cryosurgery, and brachytherapy.

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4.3 INDICATIONS FOR USE

Diagnostic Ultrasound Indications for Use Form

System/Transducer: PL2220-12

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation							
General (Track 1 only)	Specific (Tracks I & III)	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Combined* (specify)	Other** (specify)
Ophthalmic	Ophthalmic								
Fetal Imaging & Others	Fetal								
	Abdominal								
	Intraoperative (specify)								
	Intraoperative (Neuro.)								
	Laparoscopic								
	Pediatric								
	Small Organ (specify)								
	Neonatal Cephalic								
	Adult Cephalic								
	Trans-rectal								
	Trans-vaginal								
	Trans-urethral								
	Trans-esophageal								
	Muskulo-skeletal Conventional								
	Musculo-skeletal Superficial								
	Intra-luminal	Pi							
	Other (specify)								
Cardiac	Cardiac Adult								
	Cardiac Pediatric								
	Cardiac Transesophageal Adult								
	Cardiac Transesophageal Pediatric								
	Other (specify)								
Peripheral Vessel	Peripheral Vascular								
	Other (specify)								

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*Combination of each operating mode, B, M, PWD, CWD, and Color Doppler
**Amplitude Doppler and Harmonic Imaging
Additional Comments:
Subscript "a": Includes imaging for guidance of percutaneous biopsy of abdominal organs and structures (including amniocentesis).
Subscript "b": Includes imaging of organs and structures exposed during surgery (excluding neurosurgery and laparoscopic procedures).
Subscript "c": Includes thyroid, parathyroid, breast, scrotum, penis.
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Subscript "e": Includes imaging for guidance of transrectal biopsy.
Subscript "f": Includes imaging for guidance of tranvaginal biopsy.
Subscript "g": For pediatric patients.
Subscript "h": Includes imaging for guidance of transrectal biopsy, cryosurgery, and brachytherapy.
Subscript "i": Includes imaging of the biliary system (pancreato-biliary) and gastrointestinal tract (esophagus, stomach, duodenum, and large intestine).

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